REMARKS

In the aforesaid Office Action, claim 9 was rejected under 35 USC §112, second paragraph, claims 1-5, and 7-9 were rejected under 35 USC §102(b) as being anticipated by Chee et al. (EP 778037), and claim 6 was rejected under 35 USC §103(a) as being unpatentable over Chee et al. in view of Miyata et al. (U.S. Patent No. 5,439,443). Claims 1-13 are pending, and claims 10-13 are withdrawn from consideration.

The Examiner rejected claim 9 under 35 USC §112, second paragraph. Applicants have amended the claim to obviate the rejection.

The Examiner rejected claims 1-5, and 7-9 under 35 USC §102(b) as being anticipated by Chee et al., and claim 6 under 35 USC §103(a) as being unpatentable over Chee et al. in view of Miyata et al., stating that Chee et al. discloses a balloon catheter having a balloon made from an elastomeric material such as a polycarbonate polyurethane copolymer or tradename Carbothane at. column 10, lines 23-29, and that the claimed physical properties (compliance of about 0.012 to about 0.016 mm/atm and tensile elongation of about 250%, a flex modulus of about 300,000 psi and a rupture pressure of greater than 18 atm) are present in the prior art material to some extent even though not explicitly recited.

However, Chee et al. does not disclose or suggest a noncompliant catheter balloon (i.e., having a compliance of about 0.025 mm/atm or less in the working pressure range of the balloon) having a folded noninflated configuration prior to inflation in the patient, and formed at least in part of a polycarbonate based aromatic polyurethane block copolymer. Chee et al. explicitly discloses that the balloon is highly compliant (see column 4, lines 1-2 of the corresponding U.S. Patent No. 5,906,606), and that the balloon is simply inflatable from a nonfolded noninflated configuration (column 8, lines 29-50 of U.S. Patent No. 5,906,606). Chee et al. teaches away from a folded noninflated balloon configuration, stating that folded balloons

are difficult to bend, compromising catheter maneuverability. Moreover, Chee et al. discloses that the highly compliant, nonfolded balloon is formed of a polycarbonate polyurethane such as Carbothane. Carbothane is a polycarbonate based aliphatic polyurethane, as discussed in Applicants' specification and in the attached web page from Thermetics Polymer Products. The disclosure in Chee et al. of forming a highly compliant balloon from the general class of polycarbonate polyurethanes or from the specific polycarbonate based aliphatic polyurethane Carbothane does not disclose or suggest the noncompliant balloon formed of the polycarbonate based aromatic polyurethane required by Applicants' claim 1. As discussed in Applicants' specification, the preferred polycarbonate polyurethane is a polycarbonate based aromatic polyurethane such as Bionate, which unlike polycarbonate based aliphatic polyurethanes such as Carbothane provide desired characteristics such as low compliance and high rupture pressure (see Applicants' specification page 8, lines 4-6, disclosing the polycarbonate aromatic polyurethane Bionate and the polycarbonate aliphatic polyurethane Carbothane; and page 28, lines 1-13, disclosing that other polycarbonate polyurethanes including aliphatic diisocyanate based polyurethanes such as Carbothane® have been found to be not preferred in making the noncompliant balloon of the invention, due at least to the low rupture pressure and high compliance of the balloons as compared to balloons formed from Bionate®. Similarly, Chee et al. explicitly discloses that the balloon, formed for example of Carbothane, is highly compliant. Therefore, Chee et al. does not disclose or suggest the noncompliant, noninflated folded balloon formed of a polycarbonate based aromatic polyurethane, required by Applicants' claim 1.

Applicants wish to bring to the attention of the Patent Office the references listed on the attached PTO/SB.08A, and request that they be considered by the Examiner. The Information

Disclosure Statement is being submitted under 37 CFR 1.97(c)(2), and therefore the fee set forth in §1.17(p) is due.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

In light of the above amendments and remarks, applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____
Gunther O. Hanke
Registration No. 32,989

GOH:PHM:psm

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201
Enclosure: Thermedics Polymer Products webpage,
www.thermedicsinc.com/english/en/products

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

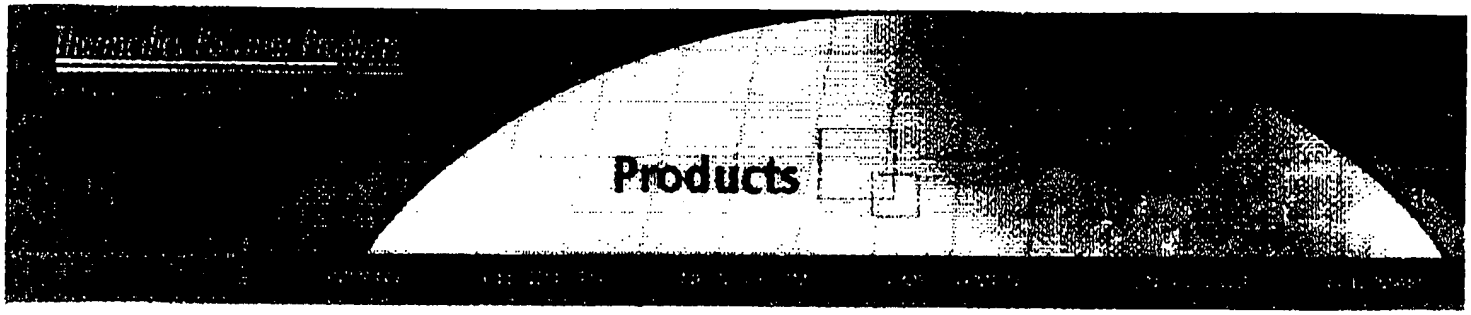
Claims 1 and 9 are amended as follows:

1. (Amended) A balloon catheter, comprising

a) an elongated shaft having a proximal end, a distal end, and at least one lumen therein; and

b) a radially noncompliant balloon having a folded noninflated configuration for introduction and advancement within a patient's body lumen, formed at least in part of a polycarbonate based aromatic polyurethane block copolymer having a compliance of less than about 0.025 mm/atm in the working pressure range of the balloon, the polycarbonate polyurethane block copolymer comprising the product of the reaction of poly(1,6-hexyl 1,2-ethylcarbonate) diol and 4,4'-methylene bisphyenyl diisocyanate (MDI) and a chain extender.

9. (Amended) The balloon catheter of claim 1 wherein the balloon has a rupture pressure which is greater than about 18 atm.



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